REMARKS

Double Patenting

The Examiner has maintained the provisional rejection of Claims 46, 48 and 49 on the grounds of obviousness type double patenting over Claims 1-4 and 6-16 of copending and commonly owned Application No. 11/198,933.

In response, the Applicants file herewith a terminal disclaimer in compliance with 37 CFR 1.321(c). As such, this rejection may be withdrawn.

Claim Rejections – 35 USC § 112

The Examiner has rejected Claims 46, 48, 49 and 53 – 61 under 35 USC § 112, first paragraph for failing to comply with the enablement requirement.

In making this rejection, the Examiner continues to assert that one of skill in the art would have to engage in undue experimentation and discovery to practice the claimed invention in view of the teachings of the specification.

With regard to enablement, MPEP § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: **is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied.** In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).
> (emphasis added)

With regard to what constitutes an "undue experimentation", MPEP § 2164.06 states:

> The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue **if the skilled artisan is given sufficient direction or guidance.**" In re Colianni, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). " 'The test is not merely quantitative, since a

> considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question **provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.**'" In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing In re Angstadt, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. United States v. Telectronics Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 490 U.S. 1046 (1989).
> *(emphasis added)*

As is clear from the excerpted sections above, it is the level of guidance provided by the specification, not the level or amount of experimentation required, that is to be assessed when determining whether the specification enables the claims. As is discussed below, the Applicants submit that the claims are fully enabled by the specification.

As discussed in previous responses, the specification clearly demonstrates that the GC-Box5 sequence in the TERT promoter has a repressive effect on TERT promoter activity in certain cells (e.g., MRC5 cells). Specifically, mutation/deletion of all or part of the GC-Box5 sequence results in increased transcription from the TERT promoter (see Examples section). The specification then provides reasonable guidance as to how one of skill in the art can use this information for a variety of practical uses. With regard to the claimed invention, the specification describes how one of skill in the art can determine whether an agent inhibits GC-Box 5 repression of TERT transcription (see especially page 32, paragraph [91] to page 34, paragraph [94]).

In making this rejection, the Examiner states that "[w]hile the methodology to add unknowns to a culture and observe an effect are simple, without a clear indication of what the observations mean, additional research on the system itself used in the assay would be required. This level of experimentation goes beyond standard optimization procedures and therefore it would be considered undue experimentation."

The Applicants submit that the experimentation that the Examiner considers "undue" is routinely engaged in by those of skill in the art of devising and performing screening assays and are related to setting up standard control experiments that allow the accurate interpretation of results obtained in the assay.

For example, one of skill in the art of screening assays knows how to identify a cell that will function appropriately in the claimed screening assay. In the case of the claimed screening assay, a cell will repress expression of the coding sequence of the expression system (i.e., one having a GC-Box5 element) but will not repress expression when the GC-Box5 element is removed or mutated (as demonstrated in the experimental section of the specification). If expression of the coding is not repressed in the cell (or if removal of the GC-Box 5 element does not reverse the inhibition) then the cell is not appropriate for use in the claimed screening assay.

Further, one of skill in the art knows how to design control experiments to appropriately interpret results such that an identified agent exhibits the claimed activity, i.e., inhibits GC-Box 5 repression of TERT transcription. For example, if an agent inhibits repression of expression from an expression system of the claimed invention, one of skill would test that agent in a control experiment employing an expression construct in which the GC-box 5 element is removed or mutated and determine whether the agent further de-represses expression. In this control experiment, the mutant construct would show higher basal level expression as compared to the experimental construct because repression mediated through the GC-box 5 element would be eliminated. However, if the de-repressive activity of the candidate agent was acting through a CG-Box 5- independent site in the construct, the agent would further de-repress expression. Other of these types of control experiments, which are routinely applied in the agent-screening art, may also be employed.

Therefore, the applicants submit that the skill in the screening art is at a level that providing a functionality for a specific site in an expression construct (e.g., the repressive activity of the GC-Box 5 element in the TERT promoter, as demonstrated in the subject specification), provides one of skill in the art with sufficient guidance as to how to proceed in setting up a screening assay for agents that impact this function.

The Applicants again stress that the claimed invention is not drawn to identifying the mechanism of action of an agent that inhibits repression though a GC-Box5 element. Rather, the claimed invention is drawn to identifying agents that, regardless of the specific mechanism of action, inhibit GC-Box5-mediated repression of the TERT

promoter. In other words, if an agent inhibits the repressive effects of the GC-Box5 repressor element in the expression system, then it meets the criteria as a GC-Box5 repressor inhibitor. Conversely, if an agent inhibits the repression of the TERT promoter through a GC-Box 5-independent mechanism, then it does not meet the criteria. As discussed above, the subject specification fully equips one of skill in the art to make this distinction.

Therefore, the Applicants submit that one of skill in the art can make and use the claimed invention without undue experimentation, and, as such, the specification fully enables the claimed invention. I view of this, the Applicants respectfully request withdrawal of this rejection.

CONCLUSION

In view of the amendments and remarks above, the Applicants respectfully submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at (650) 833-7770.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number SIER-022CON.

Respectfully submitted,
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